

EV615581113US



NP/1 CIP DIV 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Carlos A. Azpuru
Group : 2165
Applicant : Nikos Panayotatos
Application No. : 09/942,463
Filed : August 29, 2001
Confirmation No. : 9750
For : THE USE OF PROTEIN OCCLUSION FOR THE SELECTIVE
DELIVERY OF SMALL MOLECULES TO TARGETS

New York, New York
February 24, 2005

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR
SUPPLEMENTAL STATEMENT UNDER 37 C.F.R. §§1.97 AND 1.56

Sir:

Transmitted herewith is a Supplemental Statement Under 37 C.F.R. §§ 1.97 and 1.56 and copies of all documents cited therein in the above-identified application.

This Statement is submitted before the mailing date of a final action under 37 C.F.R. § 1.113, a notice of allowance under 37 C.F.R. § 1.311, or an action that otherwise

closes prosecution in the application. The Director is hereby authorized to charge payment of the \$180.00 fee under 37 C.F.R. § 1.17(p) to Deposit Account No. 06-1075. The Director is hereby authorized to charge payment of any other fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27,794)

S. Craig Rochester (Reg. No. 43,052)

Attorneys for Applicant

c/o FISH & NEAVE IP GROUP

ROPES & GRAY LLP

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SUPPLEMENTAL STATEMENT UNDER 37 C.F.R. §§ 1.97 AND 1.56

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant makes of record the following documents, copies of which are submitted herewith.* These documents were cited in a supplemental European search report, a copy of which is enclosed.

* A completed Form PTO/SB/08A listing these documents is attached hereto.



FOREIGN PUBLICATIONS

EP 0 501 309 A1

Asakawa et al.

OTHER

Allen, T.M., "Long-circulating (sterically stabilized) liposomes for targeted drug delivery," *Trends Pharm. Sci.*, 15(7):215-220 (1994).

Allen et al., "Antibody-mediated targeting of long-circulating (stealth) liposomes," *J. Liposome Res.*, 4(1):1-25 (1994).

Breeze et al., "Delivery of cytotoxic drugs to cancer patients using low density lipoprotein," *J. Controlled Release*, 28:321-322 (1994).

Citro et al., "Inhibition of leukemia cell proliferation by folic acid-polylysine-mediated introduction of c-myc antisense oligonucleotides into HL-60 cells," *Br. J. Cancer*, 69:463-467 (1994).

Kim et al., "Development of specific organ-targeting drug delivery system I: physico-pharmaceutical characteristics of thermally denatured albumin microspheres containing cytarabine," *Arch. Pharm. Res.*, 8(3):159-168 (1985).

Kramer P.A., "Albumin microspheres as vehicles for achieving specificity in drug delivery," *J. Pharm. Sci.*, 63(10):1646-1647 (1974).

Morimoto et al., "Drug-carrier property of albumin microspheres in chemotherapy. V. Antitumor effect of microsphere-entrapped adriamycin on liver metastasis of AH 7974 cells in rats," *Chem. Pharm. Bull.*, 29(5):1433-1438 (1981).

Newton D.W., "Biotechnology frontier: targeted drug delivery," *U.S. Pharmacist*, 16(4):38-39 (1991).

Sugibayashi et al., "Drug-carrier property of albumin microspheres in chemotherapy. II. Preparation and tissue distribution in mice of microsphere-entrapped 5-fluorouracil," *Chem. Pharm. Bull.*, 27(1):204-209 (1979).

Wagner et al., "Delivery of drugs, proteins and genes into cells using transferrin as a ligand for receptor-mediated endocytosis," *Adv. Drug Del. Rev.*, 14:113-135 (1994).

Applicant requests that these documents be (1) fully considered by the Examiner during the examination of this application; and (2) printed on any patent that may issue from this application. Applicant also requests that a copy of Form PTO/SB/08A, as considered and initialed by the Examiner, be returned with the next communication.

This Statement is submitted before the mailing date of a final action under 37 C.F.R. § 1.113, a notice of allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution in the application. The Director is hereby authorized to charge payment of the \$180.00 fee under 37 C.F.R. § 1.17(p) to Deposit Account No. 06-1075. The Director is hereby authorized to charge payment of any other fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,



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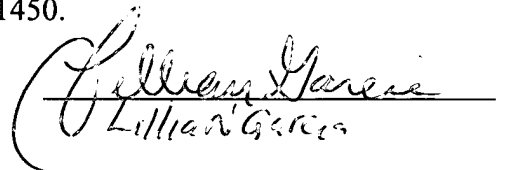
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EXPRESS MAIL CERTIFICATION

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Date of Deposit: February 24, 2005

I hereby certify that this paper/fee is being deposited with the United States Postal Service “EXPRESS MAIL POST OFFICE TO ADDRESSEE” service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.


Lillian Garcia

Enclosures:

Transmittal Letter (in duplicate);
Supplemental Statement Under 37 C.F.R. §§ 1.97 and 1.56 (in duplicate);
Form PTO/SB/08A (with cited references); and
Postcard.



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO (EV615581113US) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if known	
				Application Number	09/942,463
				Filing Date	August 29, 2001
				First Named Inventor	Nikos Panayotatos
				Art Unit	2165
				Examiner Name	Carlos A. Azpuru
Sheet	1	of	2	Attorney Docket Number	NP/1 CIP DIV 1

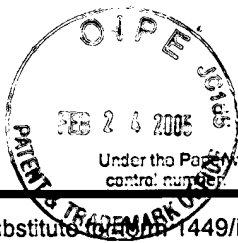
FOREIGN PATENT DOCUMENTS						
Examiner initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ^o
		Country Code ¹ - Number ² - Kind Code ³				
		0 501 309 A1	02/09/1992	Asakawa et al.		

NON PATENT LITERATURE DOCUMENTS			
Examiner initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ^o
		Allen, T.M., "Long-circulating (sterically stabilized) liposomes for targeted drug delivery," <i>Trends Pharm. Sci.</i> , 15(7):215-220 (1994).	
		Allen et al., "Antibody-mediated targeting of long-circulating (stealth) liposomes," <i>J. Liposome Res.</i> , 4(1):1-25 (1994).	
		Breeze et al., "Delivery of cytotoxic drugs to cancer patients using low density lipoprotein," <i>J. Controlled Release</i> , 28:321-322 (1994).	
		Citro et al., "Inhibition of leukemia cell proliferation by folic acid-polylysine-mediated introduction of c-myc antisense oligonucleotides into HL-60 cells," <i>Br. J. Cancer</i> , 69:463-467 (1994).	
		Kim et al., "Development of specific organ-targeting drug delivery system I: physico-pharmaceutical characteristics of thermally denatured albumin microspheres containing cytarabine," <i>Arch. Pharm. Res.</i> , 8(3):159-168 (1985).	
		Kramer P. A., "Albumin microspheres as vehicles for achieving specificity in drug delivery," <i>J. Pharm. Sci.</i> , 63(10):1646-1647 (1974).	
		Morimoto et al., "Drug-carrier property of albumin microspheres in chemotherapy. V. Antitumor effect of microsphere-entrapped adriamycin on liver metastasis of AH 7974 cells in rats," <i>Chem. Pharm. Bull.</i> , 29(5):1433-1438 (1981).	
		Newton D. W., "Biotechnology frontier: targeted drug delivery," <i>U.S. Pharmacist</i> , 16(4):38-39 (1991).	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbol as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



Substitute Form PTO 1449/PTO				Complete if known	
				Application Number	09/942,463
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Sheet	2	of	2		

NON PATENT LITERATURE DOCUMENTS			
		Sugibayashi et al., "Drug-carrier property of albumin microspheres in chemotherapy. II. Preparation and tissue distribution in mice of microsphere-entrapped 5-fluorouracil," <i>Chem. Pharm. Bull.</i> , 27(1):204-209 (1979).	
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